IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO: CASES IDENTIFIED IN **EXHIBIT A** TO THE UNDERLYING MOTION

MDL No. 2327

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF DR. NICOLETTE HORBACH, M.D.

Plaintiffs hereby move this Court to exclude or limit the expert testimony proffered by Defendant Ethicon, Inc.'s ("Defendant") expert Dr. Nicolette Horbach ("Dr. Horbach"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Horbach is a board certified physician in Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery, and Plaintiffs do not challenge her qualifications as such. However, Dr. Horbach offers opinions in this case that exceed the boundaries of her qualifications and that are founded on insufficient facts and unreliable methodology. As this Court has noted in past transvaginal mesh MDL bellwether trials, "[j]ust because an expert may be 'qualified … by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case."[1] Accordingly, Dr. Horbach should be prevented from offering testimony or opinions that exceed the boundaries permitted under *Daubert* and its progeny.

[1] *Cisson v. C.R. Bard, Inc.*, 948 F.Supp.2d 589, 612 (S.D.W.Va. 2013).

Ethicon retained Dr. Horbach to testify as a general causation expert on Defendant's TVT Retropubic product, and her General Expert Report that is the subject of this Motion is attached hereto as **Exhibit B**. Dr. Horbach's "Reliance List" served in conjunction with her Expert Report is attached hereto as **Exhibit C**. Dr. Horbach also supplied Plaintiffs' counsel with a "Sources List" at her deposition, which is attached hereto as **Exhibit D**. Dr. Horbach provided her opinions on Ethicon's TVT Retropubic over the course of two depositions, which are attached hereto as **Exhibit E**[2] and **Exhibit F**.[3] Dr. Horbach has also been deposed in her role as a general expert regarding Defendant's Prolift POP product in *Wicker v. Ethicon, Inc. et al.*, New Jersey Superior Court Case No L-6341-10-CT, Docket No. ATL-L-6951-10 on November 22, 2013, attached hereto as **Exhibit G**,[4] and again as a case specific expert for Defendant in *Schubert v. Ethicon, et al.*, Jasper County, MO Circuit Court Case NO. 10A0-CC00219 on August 21, 2013.[5]

LEGAL STANDARD

For the sake of brevity and because this Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard for exclusion of expert testimony. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of

[2] *See*, Deposition of Dr. Nicolette Horbach, taken on March 25, 2016 in MDL 2327, attached hereto as Ex. E.
[3] *See*, Deposition of Dr. Nicolette Horbach, taken on December 23, 2015 in New Jersey Superior Court case, In re: Pelvic Mesh/Gynecare Litigation, Case No. BER-L-11575-14, attached hereto as Ex. F.
[4] *See*, Deposition of Dr. Nicolette Horbach, taken on November 22, 2013 in New Jersey Superior Court Case No. L-6341-10-CT, Docket No. ATL-L-6951-10, attached hereto as Ex. G.
[5] Plaintiffs have not cited to this transcript, but will provide the Court with same if so desired.

Evidence, including but not limited to Rules 702, 403 and 104.[6] The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.[7]

ARGUMENT

I. Dr. Horbach's Testimony Should be Excluded in Its Entirety because it is Based on an Unreliable Methodology

Dr. Horbach's testimony should be excluded in its entirety because it is the product of faulty methods. A review of Dr. Horbach's Expert Report, Reliance List, and Sources List (Exs. B, C, and D) reveals dispositive issues with identifying the sources of Dr. Horbach's opinions. First, Dr. Horbach did not create her Reliance List and, as of the date of her sworn deposition testimony, she had not even reviewed the accuracy of her Reliance List and readily admits that there may be information contained in the Reliance List that she did not in fact rely on.

> Q. Thank you. Let me ask a few follow-up questions. The reliance list that you referred to, was that prepared by you or counsel for Ethicon?
>
> A. That was prepared by Ethicon.
>
> Q. Okay. And does that contain all of the articles or documents that you have reviewed and rely on in forming your opinions in this case?
>
> A. It – I have not looked at the current reliance list in this particular binder, as I just received the binder last night via Federal Express.
> …
>
> Q. Have you actually looked at all of the documents that are identified on your reliance list that is in the binder marked Exhibit 1?
>
> A: I've looked at the bulk of them;
>
> …
> Q. Okay. So is it fair to say that there may be some information on that reliance list that, for one reason or another, you have not actually reviewed and are not actually relying on in forming your opinions in this case?

[6] *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).
[7] *See Daubert*, 509 U.S. at 588; *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 141 (1999).

> A. Correct.
> ...
>
> A. If it's listed in the reliance list, it is my assumption that they were all sent to me.

Ex. E at 14:6-17; *See also, Id.* at 15:1-5; 17:15-16; 15:13-18.

Worse, Dr. Horbach had never even seen her Reliance List -- the sole basis of her expert opinions -- prior drafting and serving her Expert Report, and had yet to see it prior to providing sworn testimony.

> Q. Do you recognize this document?
>
> A. No.
>
> Q. You've never seen this document before?
>
> A. No.
>
> Q. Can you turn to the inside page, I guess the second page? I don't know if yours – mine is double-sided. Do you see it says "Nicolette Horbach Reliance List? Do you see that?
>
> A. Yes.
>
> Q. You've never seen this document before?
>
> A. Not in and of itself, no.

Exhibit F at 67:5-15; *See also, Id*. at 73:1-76:6.

Further, the vast majority of Dr. Horbach's 78-page Expert Report consists of recitations of scientific literature with no substantive citations to the literature itself.[8] The citations in Dr. Horbach's Expert Report appear to come from her Sources List (Ex. D), which was not provided to Plaintiffs until the morning of Dr. Horbach's deposition and consists of only (presumably authors') last names and years. In that Sources List, Plaintiffs are not provided with the title of the article cited, the name of the publication in which the article appeared, or with any indication

[8] *See generally,* Ex. B

as to where the information Dr. Horbach purports to quote can be found within the article. Additionally, many of the articles cited by Dr. Horbach in her report are not present in either her Reliance List or her Sources List.[9]

Finally, Dr. Horbach's report is unreliable because, in addition to the faulty citations, it contains conclusory statements with no citations to support the statement or identify the source from which the information was obtained, for example:

- "A review of 15 studies including over 30,000 women found 49% (range 24-75%) reported stress incontinence with 3-17% experiencing severe incontinence. While it is a common myth that incontinence is seen in only older women, in one survey the prevalence of any urinary incontinence in nulligravid young women (aged 16 to 30 years) was 12.6% with stress urinary incontinence reported even by young athletes.[10]

- "A review of over 20 studies evaluating the efficacy of PFE has found occasional improvement of stress incontinence, however, long-term results are disappointing. At 5 years, 25% found no change in their symptoms and up to 50% were no longer doing the exercises. At 15 years, only 25% were continuing the exercises and 50% had undergone surgical treatment of their stress incontinence. Adding bladder training and/or biofeedback to a PFE routine does not appear to improve the efficacy of PFE alone. The efficacy of electrical stimulation for stress incontinence has been inconsistent although a RCT of active stimulation versus sham stimulation did find some improvement in the treatment group."[11]

- "Reports on the efficacy of pubovaginal slings vary widely in the literature depending on the type of sling material and the definitions of success or cure, ranging from 60-93%. Autologous slings tend to have higher cure rates than allograft slings. The 20-40% failure rate reported with cadaveric fascia lata is thought to be due to autolysis and resorption of the material. The most commonly used xenograft is porcine cross-linked dermis with 1-year cure rates as low as 22% in a RCT, while another trial reported 5-year cure rates of 89%. Success rates using synthetic slings materials have approached 80-90% in some series."[12]

- "Analysis and comparison of complication rates in early and current literature is hampered by the quality of the study and the surgeon's willingness to report operative complications and/or disasters. Many of the earlier studies published on the outcome of Burch colposuspension and pubovaginal sling procedures did not specifically describe all

[9] *See*, i.e., Ex. B. at 74 ("Althaus, 2012, Johansen, 2012") neither of which is present on Ex. C or Ex. D.
[10] Ex. B at 5.
[11] *Id*. at 10.
[12] *Id.* at 19.

> complications, failed to even consider quality-of-life and sexual-function parameters, and often had rather short length of follow-up. The introduction of MUS procedures, such as the Ethicon retropubic TVT and TVT-O, corresponded with realization by clinical investigators, national specialty societies, and NIH- and industry-sponsored researchers that surgical trials must compile and publish more comprehensive and objectively defined complication rates. Thus, the more recent literature describing the complications of SUI procedures such as the MUS is more detailed than older studies published regarding the experience with traditional slings or abdominal retropubic operations. This improvement in the quality of newer studies can appear to skew comparative data on complication rates of the different procedures."[13]

- "Overall, the data indicates re-operation for mesh erosion or extrusion occurs in 1-3% of patients and in 0.6-1.2% for voiding dysfunction."[14]

This Court has held that a two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." The proponent of expert testimony does not have the burden to "prove" anything. She must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible."[15] "*Daubert* mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community."[16] Here, Dr. Horbach's testimony does not rest on a reliable foundation because she did not "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." Because Dr. Horbach does not properly cite to the sources that form the foundation of her opinions, and because Plaintiffs were supplied with a 100-page Reliance List that contains over 1,000 sources that Dr. Horbach "may" have reviewed and that

[13] *Id.* at 33.
[14] *Id.* at 36.
[15] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).
[16] *Id.*

was not created by Dr. Horbach nor seen by her prior to drafting her Expert Report or prior to giving her deposition testimony, and because her report contains conclusory statements with no citations to any source material, her opinions cannot be tested by Plaintiffs, are unreliable under *Daubert*, and should be stricken in their entirety.

II. If. Dr. Horbach is Allowed to Testify, Her Opinions Should be Limited as Follows

This Court has repeatedly held, and Fed. R. 702 requires that, in order to testify as an expert on a given subject matter in front of the jury, expert testimony is admissible only if the expert is "qualified… by knowledge, skill, experience, training, or education," and if his/her testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data;" and (3) "the product of reliable principles and methods" that (4) have been reliably applied to or "fit" the facts of the case. Here, if Dr. Horbach's testimony is not stricken entirely, it should be limited in the following areas for the following reasons.

A. Dr. Horbach is Unqualified to Testify regarding the Differences between Laser-Cut and Mechanical-Cut Mesh in Defendant's TVT Retropubic

Dr. Horbach intends to tell the jury that there is no discernable difference, either physically or *in vivo* after implantation into a woman's body, between the laser-cut mesh and the mechanical-cut mesh that have been used in Ethicon's TVT Retropubic.[17] Yet, as highlighted in her sworn testimony regarding laser-cut mesh versus mechanical-cut mesh, Dr. Horbach has not performed any testing or analysis comparing the two types of mesh, nor has she reviewed any corporate documents regarding the two types of mesh:

[17] *See*, Ex. B at 64-65.

> Q. Okay. And have you done any research or study to determine how stiff or whether there's a difference in stiffness between the laser-cut mesh and the mechanical-cut mesh?
>
> Ms. Crawford: Has she personally done any studies? Is that the question?
>
> Q. Any research, yes.
>
> A. I've had clinical experience with looking at it and working with it, but I haven't done a scientific protocol research.
>
> Q. Is the laser-cut mesh stiffer than the mechanical-cut mesh?
>
> A. From a – from a tactile standpoint, you don't really feel a lot of difference with it. I would sort of – if you were to give them to me, I wouldn't cause – I wouldn't determine that stiffness was the difference between the two.
>
> Q. Have you ever seen any internal Ethicon studies or documents related to the laser-cut mesh being stiffer than the mechanical-cut mesh?
>
> A. I don't recall.

Ex. E at 51:21-24, 52:4-18.

Further, although Dr. Horbach bases her opinions on the differences, or lack thereof, between mechanical-cut and laser-cut mesh on her "clinical experience," Dr. Horbach does not even know if she has ever implanted the laser-cut mesh *in her own practice*:

> Q. So sitting here today you don't know whether you've ever implanted a TVT laser-cut mesh, correct?
>
> A. I cannot tell you one way or the other whether or not I've done a laser-cut one versus mechanical-cut only.

Exhibit F at 93:7-9, 93:20-22.

The bottom line is that Dr. Horbach does not know the differences between laser and mechanical-cut mesh and she is therefore unqualified to testify on this topic. She has not done any testing on the two types of mesh, she has not studied any corporate documents regarding the

two types of mesh, and she does not even know if she has used the laser-cut mesh in her own practice. As such, her opinions on this topic lack a proper basis and should be excluded.[18]

B. Dr. Horbach is Unqualified to Testify as to the Pathology of Explanted Mesh and her Opinions on Mesh Pathology are Unreliable

Dr. Horbach intends to testify at trial that she has never observed degradation of mesh material in any of the pathological specimen she has removed from her patients with mesh-related complications,[19] and that the degradation of explanted meshes observed by Plaintiffs' experts via scanning electron microscope is the result of the explant process itself rather than a process that occurs within the body.[20] Dr. Horbach is also critical of the literature cited by Plaintiffs' experts in support of their position that mesh degrades in the body due to a chronic sub-clinical infection.[21] The Court should bar Dr. Horbach from proffering her pathology-related opinions because she is not qualified to testify on these topics and because her methodology is flawed with regard to the mesh specimen that she has actually looked at under a microscope. That testimony is flawed for two specific reasons: (1) she did not keep a database of her data, rather she "may" have recorded her findings in individual records, which records have not been provided to Plaintiffs' and counsel, and (2) the microscope she utilized was not powered sufficiently to view the degradation that was present.

> Q. Okay. So how many times have you reviewed mesh explants under a microscope?
>
> A. Dozens.
>
> Q. Dozens? Do you keep any database or collection of records relating to that?

[18] Dr. Horbach was also unable to recall whether laser-cut or mechanical-cut mesh was utilized in a TVT Retropubic bellwether case in which she was named an expert. *See*, Ex. E at 9:8-13-10.
[19] *See*, Ex. B at 45.
[20] *Id.* at 45, 53.
[21] *Id*. at 54-55.

A. Database relating to what my findings are of the – of that?

Q. Yes.

A. No, I don't.

Q. Yeah. Okay. So any findings you may have had you would have been recorded in the patient's individual records?

A. Yes, they – yes, they may have been recorded in the patient's individual records, yes.

Ex. F at 19:7-23.

Q. Have you ever seen degradation in any mesh explants under a microscope?

A. Have I seen it under a microscope? No.

Q. Do you know whether the microscope you were using was sufficiently powered to see degradation?

A. Probably not since I think most of the degradation reports seem to be more with, you know, scanning electron microscopy or other very specialized type of equipment and/or preparations.

Ex. F at 98:24-99:7.

Further, Dr. Horbach is not qualified to testify as an expert on the pathology of explanted mesh. There is no mention of any expertise in the field of pathology on Dr. Horbach's CV,[22] and her sworn testimony in support of Ethicon's Prolift POP product demonstrates her lack of training and specialized knowledge with respect to pathology, rendering her unqualified to provide opinions related to the timing or scope of foreign body reactions resulting from mesh implantation into the female pelvis.

Q. So at this point now in July of 2009, about nine months after the Prolift was originally put in, the pathology is showing that there is an ongoing chronic foreign body reaction; correct?

[22] *See generally*, *Curriculum Vitae* of Dr. Nicolette Horbach, attached hereto as "**Exhibit H**."

> A. It is showing that there is a foreign body reaction. My – the timing of when those giant cells showed up, whether they were early on and just persisted or, you know, a more recent event sort of implying a more chronic problem, I can't recall my pathology well enough to know how to separate that.
> "Exhibit G" at 201:12-22.

For the reasons set forth above, Dr. Horbach's pathology opinions should be excluded because they are unreliable, based on flawed methodology, and because Dr. Horbach is unqualified to render such opinions.

C. Dr. Horbach is Unqualified to Testify as to the Contents of the TVT Retropubic IFUs/DFUs and She Utilizes No Objective Basis to Form her Opinions on Medical Product Labeling

Dr. Horbach intends to testify that (1) the purpose of Defendant's IFUs/DFUs is "not to provide a complete medical education to the physician about how to perform a mid-urethral sling procedure and/or the properties and risks of using a synthetic material;"[23] (2) that the IFU/DFU provides "adequate information on the device including its use and potential risks for surgeons;"[24] (3) that it is not Defendant's responsibility to teach surgeons how to implant their TVT Retropubic devices;[25] and, (4) that it is not Defendant's responsibility to list all potential surgical risks and benefits for an individual patient in its IFU/DFUs and patient brochures.[26]Each of these opinions should be struck as Dr. Horbach is not qualified to testify regarding labeling documents because she has never worked on device labeling in her career, [27] and her methodology is fatally flawed because she does not utilize any objective basis in forming her opinions. Indeed, Dr. Horbach concedes that the only bases for her IFU opinions are her own personal and subjective standards and that she didn't bother to consult any published standards,

[23] *See*, "Exhibit B" at 47.
[24] *Id.* at 48-49.
[25] *Id.* at 49.
[26] *Id.* at 78.
[27] *See*, Ex. F at 51:18-52-2. *See also, generally,* Ex. H.

the applicable FDA regulations or even Ethicon's internal standards related to IFUs.[28] Couple that flawed methodology with her complete lack of experience in drafting medical device IFUs, and any opinion she could tender on the subject is unreliable and should be struck:

> Q. In formulating your warnings opinions in this case what standards did you apply?
>
> A. I applied the clinical standards for determining – determining how much information is necessary or not necessary in a written document versus the current information that was in the medical literature regarding the potential complications of incontinent surgeries with or without the use of other synthetic mesh materials.
>
> Q. Okay. Whose clinical standards were those?
>
> A. Those are the clinical standards based on my position in national organization of having written guidelines for education and training. Those are based on my work with having been recognized as an expert by the American Board of Ob/Gyn, The American College of Obstetrics and Gynecology, the NIH, The American Urogynecologic Association, and – so, yeah, I think that – it's that type of expertise.
>
> Q. Okay. So I didn't ask about expertise. I'm asking about standards, doctor. Did you apply your own personal standards in deciding whether the labeling was adequate?
>
> A. I applied what I believed to be the clinical medical standards in the community – in the medical community for our field.
>
> Q. Okay. Are those published anywhere?
>
> A. No.
>
> Q. Did you consult any published standards in formulating your warnings opinions?
>
> A. No.
>
> Q. Did you consult any FDA guidance documents with respect to warnings for medical devices?

[28] Dr. Horbach brought a 1991 FDA General Program Memorandum regarding device labeling guidance to her deposition on March 25, 2016, but it is clear that Dr. Horbach did not rely on that document in forming the opinions in her expert report. *See*, Ex. E. at 23:13-24:3.

A. No.

Q. Did you look at any Ethicon internal standards for warnings on medical devices?

A. No.

Ex. F at 52:21-54:11 (Objections omitted).

As this Court has previously held, "an expert's inability to identify an applicable standard renders her opinion unreliable. ('Without a reliable, objective basis for [expert] testimony, stemming from identifiable industry standards, codes, publications or training, it must be precluded under Rule 702.')"[29] Dr. Horbach has not identified any particular standards upon which she bases her labeling opinions, and her IFU opinions are therefore unreliable and must be excluded.

D. Dr. Horbach is Unqualified to Testify as to the Material Characteristics of Polypropylene Mesh

Dr. Horbach intends to testify to the jury about the material properties of polypropylene mesh and the effects that different material mesh properties have on the behavior of mesh once implanted into the female pelvis. For example, Dr. Horbach intends to tell the jury about (1) different types of mesh fibers, (2) sizes of mesh fibers, (3) types of mesh weaves, (4) pore sizes, (5) mesh density, and (6) mesh surface area.[30] Dr. Horbach also plans to tell the jury that the mesh used in Ethicon's TVT Retropubic product is safe and suitable for use as a permanent implant in the female pelvis,[31] that Ethicon's mesh does not degrade or contract, and that there are no alternative feasible designs to Defendant's mesh that would be safer than the mesh that is

[29] *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *29 (S.D.W. Va. May 5, 2015), *citing*, *Lasorsa v. Showboard: The Mardi Gras Casino*, No. 07-4321, 2009 WL 2929234, at *5 (D.N.J. Sept. 9, 2009).
[30] *See*, Ex. B at 18-19.
[31] *Id.* at 52.

presently used in Defendant's TVT Retropubic.[32] Once again, Dr. Horbach is unqualified to give these opinions and there is no reliable basis for her opinions.

As an initial matter, there is no evidence of specialized knowledge of materials science on the face of Dr. Horbach's CV.[33] Further, Dr. Horbach herself admits that she is not an expert in the biochemistry of materials.[34] She also admits that she has never designed a mesh sling for use by other doctors,[35] and that she is not a biomedical engineer or a materials engineer.[36] Nonetheless, despite clear admissions that she is not an expert on these matters, Ethicon still proffers Dr. Horbach to testify as to the safety of the material design of Ethicon's TVT Retropubic. Because Dr. Horbach does not possess the requisite "knowledge, skill, experience, training, or education" to testify about the material properties of the polypropylene mesh used in Ethicon's TVT Retropubic, her opinions on these topics should be excluded

Further, Dr. Horbach should not be allowed to testify as to the material properties of mesh because her opinions have no reliable basis. Dr. Horbach's only experience as an expert in materials comes from her experience as "as a clinical expert in using a material in mesh within a clinical setting, not in the, necessarily, the biochemistry, shall we say, of materials."[37] In *Cisson v. C.R. Bard, Inc.*, with regard to Dr. Shull's materials opinions, this Court held that Dr. Shull's opinions lacked a reliable basis because they were based on his personal experiences and observations.[38] Similarly here, Dr. Horbach's materials opinions fail due to a lack of reliability

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[32] *Id.* at 53, 58, 61-64.
[33] *See generally*, Ex. H
[34] *See*, Ex. F at 77:1-4.
[35] *Id*. at 148:14-16.
[36] *Id*. at 149:5-8.
[37] *Id.* at 77:1-4.
[38] *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013)

as they are merely based on her own personal experiences and observations regarding a topic for which she is unqualified to render expert opinions.

E. Dr. Horbach's Opinions that Do Not Properly Identify the Source of the Opinion Should be Excluded

Plaintiffs have already addressed the inadequacy of the citations in Dr. Horbach's report *supra* in Section I of this brief. Should the Court elect not to exclude Dr. Horbach's testimony in its entirety based on Plaintiffs' arguments, the Court should at least exclude Dr. Horbach's opinions that do not provide identifying source information for the opinions.

CONCLUSION

For each of the reasons set for above, Plaintiffs respectfully request that this Honorable Court preclude Dr. Horbach from offering any opinions at trial, and specifically from offering opinions on the following topics:

1. The physical and clinical differences between machine-cut and laser-cut mesh;
2. The pathological findings of explanted mesh;
3. Medical Device Product Labeling;
4. The Biomaterial properties of mesh; and,
5. Opinions with no identifying source information

Dated: April 21, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, a true and correct copy of this document was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff, Esq.